REMARKS

In an office action mailed July 29, 2003, claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, and 62-76 have been rejected under 35 U.S.C. 112; claims 1-7, 9-16, 17-22, 24-31, 47-52, 59-61, 62-65 and 69-96 have been rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-16, 17-31, and 47-96 have been rejected under 35 U.S.C. §103(a).

In response, Applicants have cancelled claims 5, 7, 8, 10-12, 21-23, 25-27, 32-46, 51-53, 55-57, and 62-96, and amended claims 1, 17 and 47. In addition, Applicants provide the following remarks and terminal disclaimers. Claims 1-4, 6, 9, 13-20, 24, 28-31, 47-50, 54, and 58-61 are pending in the application.

I. Amendments to Claims

In the office action, the Examiner notes that Applicants previously elected the invention of Group I (claims 1-31 and 47-96), and that claims 34-43 have been withdrawn from consideration as being drawn to a non-elected invention.

Applicants believe that the Examiner may have made an error in what claims should be withdrawn as being drawn to a non-elected invention. It appears that claims 32-46 should be withdrawn. In the interest of moving the application towards allowance, Applicants have cancelled claims 32-46, reserving the right to pursue these claims in a continuation application.

The pending claims have been amended so as to recite methods for treating various aspects of addiction with a composition consisting essentially of topiramate. Applicants

have discovered that topiramate shows significantly positive effects in the treatment of addiction. See examples 13 and 14 of the application.

II. Rejections Under 35 U.S.C. §112, First Paragraph

In the office action, claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 have been rejected under §112, first paragraph. According to the Examiner, "the specification does not reasonably provide enablement for the employment of any compound employed in any composition that increases central nervous system GABA levels in a mammal for the claimed methods."

At the bottom of page 6 of the office action, the Examiner acknowledges that one particular compound, topiramate, employed in a composition for the treatments claimed, was tested in the working examples provided.

In response, and in the interest of moving the application towards allowance, Applicants have amended the claims to recite methods for treating various aspects of addiction with a composition consisting essentially of topiramate.

Accordingly, Applicants respectfully request that the rejection of claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 under §112 be reconsidered and withdrawn.

Claims 62-76 (directed towards a method for **preventing** addiction to drugs) have also been rejected under §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, and in the interest of moving the application towards allowance, claims 62-76 have been cancelled, with the right to pursue them at a later time or in a continuation application.

Accordingly, Applicants respectfully submit that the rejection under §112 of claims 62-76 has been rendered moot.

III. Double Patenting

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,057,368.

The claims of the `368 patent are directed to methods of changing addiction related behavior of a primate by administering gamma vinylGABA (GVG). There is no disclosure in the `368 patent for treating addiction with topiramate. The claims of the present invention have been amended as to recite only topiramate.

Therefore, Applicants respectfully submit that the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,057,368 has been rendered moot.

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of U.S. Patent No. 6,541,520.

Claims 1-4, 6, 13-16, 17-20, 28-31, 47-50, 59-61, 62-65 and 73-76 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,323,239.

Claims 1-7, 9-16, 17-22, 24-31, 47-52, 54-67, and 69-96 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,395,783.

Applicants also bring to the Examiner's attention that there exist another related issued patent that claims methods for treating addiction with GVG and discloses topiramate (6,593,367); and two other co-pending, related applications that discloses topiramate and claim methods for treating nicotine addiction with gamma vinyl GABA (09/189,166) and methods for treating addiction to various drugs with topiramate (09/933,157).

The Examiner has indicated that filing a Terminal Disclaimer may be used to overcome the provisional obviousness-type double patenting rejections. Therefore, terminal disclaimers are being submitted herewith with respect to the present invention and the inventions claimed in the above issued patents and applications.

Accordingly, Applicants respectfully submit that the rejections based on the judicially created doctrine of obviousness-type double patenting have been overcome.

IV. Rejections Under 35 U.S.C. §103

Claims 1-31 and 47-96 have been rejected under §103(a) as being unpatentable over U.S. Patent No. 5,189,064 to Blum et al. and U.S. Patent No. 3,639,607 to Phillips in view of U.S. Patent 5,302,583 to Costa et al., and U.S. Patent No. 5,538,956 to Minchin et al., and U.S. Patent No. 5,332,736 to Carmosin et al. All of the cited documents were disclosed in an information disclosure statement filed by Applicants.

According to the Examiner, "Blum discloses that GABA and GABA agonists are useful in methods for the treatment of addiction or abuse of drugs such as cocaine and alcohol since GABA agonists increase GABA levels in a mammal."

The Examiner also states that Phillips discloses that anticonvulsants are known to be useful broadly in methods of treatment of tobacco addiction.

The Examiner recognizes that neither Blum nor Phillips expressly disclose using the particular GABA agonists disclosed in the present application or their effective amounts in methods of treating addiction-related behavior.

Costa, Minchin and Carmosin have been cited by the Examiner for disclosing that particular compounds (e.g. valproic acid, gabapentin, fengabine, progabide and topiramate) are known to be GABA agonists. Therefore, the Examiner contends that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular GABA and GABA agonists in methods of treating addiction-related behavior. Applicants respectfully disagree.

Firstly, Applicants have amended the claims so as to recite methods of treating various aspects of addiction by administering a composition consisting essentially of topiramate. Blum relates only to the treatment of cocaine addiction with a compound that increases endogenous brain endorphin and enkaphalin levels, optionally with, among other things, a GABA precursor. See the title; column 1, lines 12-16; column 3, lines 34-38 and the claims.

Blum points out that it is known that GABA as well as GABA agonists will reduce seizure activity during alcohol withdrawal in rodents. See column 3, lines 64-66. Use of GABA and GABA agonists to treat seizures has been known for quite some time. Importantly, Blum does not disclose or suggest treating the various aspects of addiction claimed in the present invention by administering a composition consisting essentially of topiramate.

Contrary to the Examiner's statements concerning Blum, Blum does not disclose that GABA and GABA agonists are useful in methods for the treatment of addiction or abuse of drugs such as cocaine and alcohol. Blum teaches a method for treating cocaine addiction by administering a compound that increases endogenous brain endorphin and enkephalin levels in an attempt to regulate dopamine synthesis and release. See column 3, lines 46-60.

In one embodiment, Blum discloses co-administering a GABA precursor for the purpose of controlling possible convulsions or seizures that may result from cocaine use. See column 4, lines 37-65. Blum does not disclose or suggest treating various aspects of addiction claimed in the present invention by administering a composition consisting essentially of topiramate.

Phillips discloses a method for treating the tobacco smoking habit with "a drug of the class effective to prevent or reduce convulsions." See column 1, lines 64-68. Phillips discloses numerous drugs of the class contemplated and discloses that derivatives of hydantion are particularly preferred. See column 2, lines 5-7, and column 2, lines 39-53.

Phillips does not disclose or suggest using topiramate to treat the various aspects of addiction presently claimed. Topiramate is not a derivative of hydantoin. Rather, topiramate is a sulfamate-substituted monosaccharide.

Costa, Minchin and Carmosin have been cited by the Examiner for disclosing that particular compounds (e.g. valproic acid, gabapentin, fengabine, progabide and topiramate) are known to be GABA agonists. Neither Costa, Minchin or Carmosin disclose or suggest the claimed method.

Applicants respectfully traverse the above rejection under §103. Applicants submit that the burden of establishing a *prima facie* case of obviousness has not been met because there is no suggestion or motivation to combine the referenced teachings.

Additionally, upon combining the teachings of Blum and Phillips with Costa, Minchin and Carmosin, one would not arrive at the claimed invention.

In order to establish a *prima facie* case of obviousness, one of the criteria to be met is that the prior art reference must teach or suggest all of the claim limitations. See MPEP §2142.

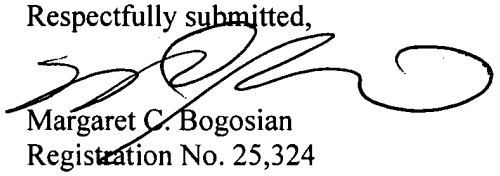
Applicants` have demonstrated the importance of administering topiramate when treating the various aspects addiction claimed in the present invention.

Upon combining the teachings Blum and Phillips with Costa, Minchin, and Carmosin, all of Applicants` claimed limitations are not taught or suggested. .Therefore, based on the foregoing discussion, Applicants` claimed invention is not obvious over Blum and Phillips in view of Costa, Minchin, and Carmosin.

Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under §103 based on Blum and Phillips in view of Costa, Minchin and Carmosin.

In light of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance. If the Examiner believes a telephone discussion with Applicant's representative would be of assistance, he is invited to contact the undersigned at his convenience.

Respectfully submitted,



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